DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 23, 2011 has been entered.

Claim Objections

2. Claims 79 and 80 are objected to because of the following informalities:

Claims 79 and 80 are currently claimed as being dependent on claim 78, a cancelled claim. For examination purposes, Examiner assumes Applicant intended claims 79 and 80 to be dependent on claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4,6-8,10-11,13-24,30-31,33-34,36-43,69-70,72-77,80,82,84 and 86-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan (US Patent No. 6,936,003) in view of Bouton (US Pub No. 2003/0036674).

With regards to claims 1,18,21,69, 41,71 and 82 Iddan discloses an endoscope and a method for tissue characterization using the endoscope, which comprises:

an intracorporeal portion, configured for insertion into a body, and including:

a nonirradiative electromagnetic sensor for tissue characterization (column 3, lines 28-51; column 3, line 62-column 4, line 25), configured to be placed proximally to an edge of a tissue for characterization, said characterization being without penetration by said non-irradiative electromagnetic sensor of the tissue being characterized (column 5, lines 6-19, lines 36-62; column 3, lines 1-6; column 14, lines 51-55; note that placement of endoscope/sensor in body (i.e. blood vessel) results in sensor being placed proximally to edge of a tissue (i.e. vessel wall) for characterization); and

a communication line, on which the electromagnetic sensor is mounted (column 4, lines 39-59, see Figure 1A); and

an extracorporeal portion, configured for manipulating the intracorporeal portion (column 3, lines 18-27; column 5, lines 6-19); and

a control station (column 5, lines 21-62). See Figure 1A.

However, they fail to disclose that the non-irradiative electromagnetic sensor is further configured to produce electromagnetic fields, wherein said characterization is performed by measurement of reflections of said electromagnetic fields following interaction with said tissue.

Bouton discloses a sensor element for receiving electromagnetic waves into body tissue that is an improved sensor for detecting elevated or otherwise abnormal levels of fluids in living tissue and can be used to detect tumors (pg. 2, paragraph [0014]-[0015]). The sensor element can be constructed to have an antenna element, which may serve as an electromagnetic source that transmits/produces electromagnetic waves into tissue in an area of interest and also receives reflected electromagnetic waves (i.e. single antenna acts as both the source and the sensing element) (pg. 2, paragraph [0017]; pg. 6, paragraph [0070]). The received reflected signal is used to characterize the tissue pg. 6, paragraph [0075]-[0076]; pg. 5, paragraph [0068]).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Iddan to substitute the electromagnetic sensor disclosed by Iddan with the electromagnetic sensor taught by Bouton, as Iddan requires a sensor that characterizes tissue and Bouton teaches such a sensor that can be used for detecting the presence of tumors in living tissue (pg. 2, paragraph [0014]). The substitution of one known element for another yields predictable results to one of ordinary skill in the art.

With regards to claims 2 and 22, Iddan discloses that the communication line is formed as an instrument bundle (column 4, lines 39-59; see Figure 1A).

With regards to claims 3 and 23, Iddan discloses that the instrument bundle extends beyond a distal-most end of the endoscope, with respect to an operator (column 3, line 18-51; column 3, line 62-column 4, line 25; see Figure 1A) , and a distal-most end of the instrument bundle may be manipulated, extracorporeally, to bring the

electrmagnetic sensor to contact with tissue, for characterization (column 5, lines 6-19, lines 36-62).

With regards to claim 4, Iddan discloses that the intracorporeal portion further includes an instrument channel, and the electromagnetic sensor for tissue characterization is inserted into the instrument channel (column 4, lines 39-59; see Figure 1A).

With regards to claims 6, 24, 30 and 86, Iddan discloses that the endoscope further includes a catheter, wherein the electromagnetic sensor is inserted into the catheter, and the catheter is inserted into the instrument channel (column 3, lines column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-59; see Figure 1A).

With regards to claims 7, 31 and 87, Iddan discloses that the catheter extends beyond a distal-most end of the endoscope, with respect to an operator, and a distal-most end of the catheter may be manipulated independently of the distal-most end of the endoscope (column 3, lines column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-59; see Figure 1A).

With regards to claim 8, Iddan discloses that the intracorporeal portion further includes an optical channel for an optical instrument (column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-67; see Figure 1A).

With regards to claims 10-11 and 33-34, Iddan discloses that the intracorporeal portion further includes a second instrument (i.e. optical sensor, temperature sensor, impedance sensor, etc.) (column 3, line 28-column 4, line 25; see Figure 1A).

With regards to claims 13, 17,36,40, Iddan discloses that the intracorporeal portion is designed for motion in a body lumen (i.e. a gastrointestinal tract, a colon, a vagina, a uterus, a blood vessel, etc.) (column 3, lines 1-6; column 5, lines 6-19, 36-62).

With regards to claims 14 and 38-39, Iddan discloses that the intracorporeal portion is designed for reaching the lumen by percutaneous insertion (column 3, lines 1-6).

With regards to claim 15, Iddan discloses that the endoscope is configured for characterizing a tissue along the lumen wall (column 14, lines 49-55).

With regards to claims 16 and 37, Iddan discloses that the endoscope is configured for characterizing a tissue outside the lumen, by penetrating the lumen wall (column 3, line 62-column 4, line 25; column 14, lines 38-55; column 3, lines 1-6).

With regards to claims 19-20 and 42-43, Bouton discloses that the tissue characterization relates to the detection of a malignancy and the detection of a pre-cancerous state (pg. 2, paragraph [0014]-[0015]).

With regards to claim 70, Iddan discloses that the control station further includes at least one of a control unit, control buttons, a keyboard, a read/write device, a signal analyzer, and a display screen (column 5, lines 21-62).

With regards to claims 72-74, Iddan discloses that the second instrument is configured for taking a biopsy sample, localized surgery, and dispensing medication (column 3, lines 28-51; column 3, line 62-column 4, line 25).

With regards to claims 75-77, Iddan discloses that the intracorporeal portion includes a cutting tool (column 3, lines 28-51; column 3, line 62-column 4, line 25).

With regards to claims 80 and 84, Bouton discloses that heir sensor includes a resonating element (20, 400,420) configured to be placed proximally to an edge of the tissue, without penetrating the tissue (pgs.5-6, paragraph [0070], [0073]; pg. 8, paragraph [0087]). The sensor has a conductive structure (420,440,450) having a diameter-equivalent D (400w), which defines a cross-sectional area of the resonating element, on a plane substantially parallel with the edge of the tissue (see Figure 7D; pg. 8, paragraph [0090]). The resonating element is configured to resonate at a free-air wavelength range of between about λ and about 10 λ, wherein λ is at least about ten times the diameter-equivalent D (pg. 10, paragraph [0109]; pg. 11, paragraph [0121]; pg. 6, paragraphs [0074]-[0078], note that other possible wavelength configurations are possible by adapting the design of the antenna). Upon receiving a signal in the range of between λ and about 10 λ, the sensor is configured to induce electric and magnetic fields, in a near zone, in the tissue, the near zone being a hemisphere having a diameter of substantially D, beginning with the edge of the tissue, while causing negligible radiation in a far zone, so that the tissue, in the near zone, effectively functions as part of the resonating element (pg. 2, paragraph [0016]; pg. 6, paragraph [0074]-[0075]; pg. 7, paragraph [0080]; pgs. 10-11, paragraph [0112]; see Figures 13-16, 18 and 21-22), and wherein different tissue types have different resonating responses to the electromagnetic sensor, so that tissue, in the near zone, may be categorized by the resonating response to the nonirradiative electromagnetic sensor (pg. 6, paragraph [0075]-[0076]; pg. 5, paragraph [0068]).

With regards to claims 88-91, Iddan discloses that the distal-most end of the catheter is manipulated electronically and manually (column 5, lines 6-62).

5. Claims 5, 25-29, 44-60 and 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan in view of Bouton as applied to claims 4 and 24 above, and further in view of Ouchi (US Patent No. 6,203,533).

As discussed above, the above combined references meet the limitations of claim 4 and most of the limitations of claims 44-45,51-60 and 62. Further, with regards to claims 25-29,44,46-51,53-58 and 63-68, Iddan discloses that their method further includes a second instrument inserted in the endoscope and performing a second procedure with the second instrument, wherein the second procedure includes taking a biopsy sample, a localized surgery, dispensing medication, and characterizing the tissue by an additional sensor (column 3, line 28-column 4, line 25).

However, they do not specifically disclose that the electromagnetic sensor for tissue characterization may be removed from the instrument channel and replaced with the second instrument.

Further, they do not specifically disclose inserting a guide wire to the location of the characterized tissue and inserting the second instrument into the instrument channel along the guidewire.

Ouchi discloses an injector instrument, for insertion into a forceps channel of an endoscope, which is inexpensive, is easily fed around bends in a forceps channel, is sufficiently small to be inserted into even a thin forceps channel and is easily cleansed

and disinfected (column 4, lines 26-30, 58-67). The injector instrument is removably inserted through a forceps channel of an endoscope (column 10, lines 11-16; column 14, lines 1-3). A guide tube can be inserted in the forceps channel of the endoscope and the injector instrument inserted along the guide tube (column 20, lines 21-27). They further disclose that other treatment accessory devices can be inserted in the forceps channel and by doing so the size of the endoscope is not increased (column 23, lines 23-30; column 24, lines 26-45; column 29, lines 31-39).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have the electromagnetic sensor be removed from the instrument channel and replaced with the second instrument and insert the second instrument into the instrument channel along an inserted guide wire, as taught by Ouchi, in order to be able to effectively clean and disinfect the electromagnetic sensor, be able to use a variety of instruments without increasing the size of the endoscope and properly position the second instrument (column 4, lines 26-30,58-67;column 29, lines 31-39).

6. Claims 9, 12, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan in view of Bouton as applied to claims 9, 10, 21 and 33 above, and further in view of Nevo et al. (US Pub No. 2003/0187347).

As discussed above, the above combined references meet the limitations of claims 9,10,21 and 33. Iddan further disclose that their method includes inserting an optical instrument (column 3, lines 28-51).

However, they do not specifically disclose that the second instrument, such as an optical instrument, is configured to sense/visually observe the electromagnetic sensor as it makes contact with a tissue.

Nevo et al. discloses that their invention includes the use of a separate set of tracking coils for tracking purposes (i.e. electromagnetic sensor), and a separate set of imaging coils for imaging purposes (i.e. MR sensor) (pg. 6, paragraph [0076], pg.3, paragraph [0029]). The control system controls the set of tracking coils to sense and indicate the location and orientation of the probe within the body cavity and controls the set of imaging coils to image selective areas within the body cavity (pg. 3, paragraphs [0028]-[0029]).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Iddan to have the second instrument be configured to sense/image the electromagnetic sensor, as taught by Nevo et al., in order to enable the instrument to characterize selected areas within the body cavity (pg.3, paragraph [0028]-[0029]).

7. Claims 79 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan in view of Bouton as applied to claims 1 and 82 above, and further in view of Hashimshony (US Pub No. 2003/0187366).

As discussed above, the above combined references meet the limitations of claims 1 and 82. However, they do not specifically disclose that the nonirradiative electromagnetic sensor is configured for: applying an electrical pulse to the tissue;

generating an electrical fringe field in a near-field zone of the tisssue, so as to produce a reflected pulse from the near-field zone of the tissue with negligible radiation penetrating the tissue; and detecting the reflected electrical pulse.

Hashimshony disclose a method and apparatus for examining tissue in order to differentiate the examined tissue from other tissue (i.e. differentiate between cancerous and normal, healthy tissue) according to the dielectric properties of the examined tissue (pg. 1, paragraph [0001]). They disclose that their apparatus comprises of applying an electrical pulse to the tissue to be examined via a probe such that the probe generates an electrical fringe field in the examined tissue and produces a reflected pulse therefrom, with negligible radiation penetrating into other tissues or biological bodies near the examined tissue; detecting the reflected electrical pulse; and comparing electrical characteristics of the reflected electrical pulse with respect to the applied electrical pulse to provide an indication of the dielectric properties of the examined tissue (pg. 2, paragraphs [0017]-[0018]; pg. 5, paragraph [0059]; see Figures 4 and 6).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the sensor taught by Hashimshony substitute for the electromagnetic sensor of the above combined references, as the above combined references require a sensor that can provide information of the surrounding tissue and Hashimshony teaches such a sensor.

Response to Arguments

8. Applicant's arguments with respect to claims 1-51,53-59,62-70,72-77,79-80,82-84 and 86-91 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. F./
Examiner, Art Unit 3768

/LONG V. LE/
Supervisory Patent Examiner, Art Unit 3768